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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,624	01/22/2002	Sean H. Adams	09800081-0066	4963

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EXAMINER	
RAMIREZ, DELIA M	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/055,624	ADAMS ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 1-31 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I-III. Claims 1-4, drawn in part to a brown fat inducible thioesterase (BFIT) comprising SEQ ID NO: 2, 4, or 6, respectively, classified in class 435, subclass 196, (i.e. Group I is directed to a polypeptide comprising SEQ ID NO: 2, Group II is directed to a polypeptide comprising SEQ ID NO: 4, and Group III is directed to a polypeptide comprising SEQ ID NO: 6).

IV-VI. Claims 5-9, 25-26, drawn in part to a polynucleotide encoding the BFIT of SEQ ID NO: 2, 4, or 6, respectively, classified in class 536, subclass 23.2.

VII-IX. Claim 10, drawn in part to an antibody which binds to the polypeptide of SEQ ID NO: 2, 4 or 6, respectively, classified in class 530, subclass 387.1.

X-XII. Claim 11, drawn to a method of treating a metabolic disease with a polypeptide comprising SEQ ID NO: 2, 4 or 6, respectively, classified in class 514, subclass 2.

XIII-XV. Claims 12-14, drawn in part to a method of treating a metabolic disease with a polynucleotide encoding a polypeptide comprising SEQ ID NO: 2, 4, or 6, respectively, classified in class 514, subclass 44.

XVI-XVIII. Claims 15-16, drawn in part to a method of quantifying BFIT by using an antibody which binds a polypeptide comprising SEQ ID NO: 2, 4, or 6, respectively, classified in class 436, subclass 512.

XIX-XXI. Claims 17-19, 24, drawn in part to a method of measuring BFIT agonist or antagonist activity with a polypeptide comprising SEQ ID NO: 2, 4, or 6, respectively, classified in class 436, subclass 86.

XXII-XXIV. Claims 20-23, drawn in part to a method of measuring BFIT transcription up-regulation or down-regulation activity of a compound with a polynucleotide encoding a polypeptide comprising SEQ ID NO: 2, 4, or 6, respectively, classified in class 436, subclass 94.

XXV-XXVII. Claims 27-29, drawn in part to a method of screening a patient for a metabolic disease with a polypeptide comprising SEQ ID NO: 2, 4, or 6, respectively, classified in class 436, subclass 62.

XXVIII-XXX. Claims 30-31, drawn in part to a method of screening a sample for a BFIT mutation using a polynucleotide which encodes a polypeptide comprising SEQ ID NO: 2, 4, or 6, respectively, classified in class 436, subclass 94.

The inventions are distinct, each from the other because of the following reasons:

2. Groups I-IX each comprise a chemically unrelated structure capable of separate manufacture, use, and effect. The DNA in Groups IV-VI each comprises an unrelated nucleic acid sequence, whereas the proteins of Groups I-III and Groups VII-IX each comprise an unrelated amino acid sequence. The DNA of Groups IV-VI has other uses besides encoding the proteins of Groups I-III, such as a hybridization probe or in gene therapy. The proteins from Groups I-III can be used in materially different methods other than to make the antibodies of Groups VII-IX, such as in therapeutic or diagnostic methods (e.g. in screening). Further, the proteins of Groups I-III can be prepared by processes which are materially different from recombinant expression of the DNA of Groups IV-VI, such as by chemical synthesis, or by isolation and purification from natural sources. The antibodies of Groups VII-IX cannot be made by recombinant expression of the DNA of Groups IV-VI.

3. Inventions I-III, X-XII, XIX-XXI, and XXV-XXVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the proteins of Inventions I-III can be used in the different methods of Inventions X-XII, XIX-XXI, and XXV-XXVII as well as in eliciting antibodies.

4. Inventions IV-VI, XIII-XV, XXII-XXIV, and XXVIII-XXX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotides of Inventions IV-VI can be used in the distinct methods of Inventions XIII-XV, XXII-XXIV, and XXVIII-XXX, as well as in the recombinant production of the proteins of Inventions I-III.

5. Inventions VII-IX and XVI-XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Inventions VII-IX can be used in the methods of Inventions XVI-XVIII as well as in the purification of the proteins of Inventions I-III.

6. Inventions I-III, XIII-XVIII, XXII-XXIV and XXVIII-XXX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the proteins of Inventions I-III are neither used nor made by the methods of Inventions XIII-XVIII, XXII-XXIV or XXVIII-XXX.

7. Inventions IV-VI, X-XII, XVI-XXI, and XXV-XXVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotides of Inventions IV-VI are neither used nor made by the methods of Inventions X-XII, XVI-XXI, or XXV-XXVII.

8. Inventions VII-IX, X-XV, and XIX-XXX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies of Inventions VII-IX are neither used nor made by the methods of Inventions X-XV or XIX-XXX.

9. Inventions X-XXX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions X-XXX comprise different steps, may use different products and produce different results.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments

submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

12. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143).

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 872-9306. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
June 9, 2004

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